

LIST OF REFERENCES CITED BY APPLICANT

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ATTY. DOCKET NO.
 11808-045-999
 (CAM: 120024-999045)

APPLICATION NO.
 10/563,418

APPLICANT
 Jungles *et al.*
FILING DATE
 July 24, 2007

ART UNIT
 1614
U.S. PATENT DOCUMENTS

*Examiner Initials		Document Number	Date mm-dd-yyyy	Name of Patentee or Applicant of Cited Document	
	A01	4,778,794	10-18-1988	Naruse et al.	
	A02	5,753,656	05-19-1998	Sakai et al.	
	A03	6,288,067	09-11-2001	Okamura et al.	
	A04	6,410,535	06-25-2002	Kashiwagi et al.	
	A05	6,417,205	07-09-2002	Cooke et al.	
	A06	2004/0058896	03-25-2004	Dietrich et al.	
	A07	2006/0035900	02-16-2006	Moser et al.	
	A08	2006/0040946	02-23-2006	Oppenheimer et al.	
	A09	2008/0207624	08-26-2008	Sugita et al.	

FOREIGN PATENT DOCUMENTS

*Examiner Initials		Foreign Patent Document Country Code, Number, Kind Code (if known)	Date mm-dd-yyyy	Name of Patentee or Applicant of Cited Document		T
	B01	EP 1757293	02-28-2007	Daiichi Asubio Pharma Co. Ltd.		
	B02	WO 2005/107759	11-17-2005	Daiichi Asubio Pharma Co. Ltd.		
	B03	WO 2006/063215	06-15-2006	BioMarin Pharmaceutical Inc.		
	B04	WO 2007/067570	06-14-2007	BioMarin Pharmaceutical Inc.		

NON PATENT LITERATURE DOCUMENTS

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C01	FDA Center for Drug Evaluation and Research (CDER) Draft Guidance for Industry ANDAs: Pharmaceutical Solid Polymorphism Chemistry, Manufacturing, and Controls Information; December 2004	
	C02	"Tetrahydrobiopterin tablets" by Schircks Laboratories, August 15, 2003.	
	C03	"Data Sheet – Tetrahydrobiopterin" by Schircks Laboratories, September 16, 2003	
	C04	"Summary of product characteristics-Tetrahydrobiopterin 10 mg/50 mg Tablets" by Schircks Laboratories, January 7, 2004.	
	C05	"Certificate of Analysis" by Schircks Laboratories, March 11, 2005	
	C06	"Tetrahydrobiopterin tablets" by Schircks Laboratories, January 8, 2008.	
	C07	"Statement for the Record" from the file history of USSN 10/990,316, February 25, 2008	
	C08	"Summary of product characteristics-Tetrahydrobiopterin tablets" by Schircks Laboratories, March 31, 2008.	

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	C09	Office Action mailed 08/06/08, U.S. Application No. 12/106,621	
	C10	Office Action mailed 10/20/08, U.S. Application No. 12/106,621	
	C11	Interview Summary mailed 10/31/08, U.S. Application No. 12/106,621	
	C12	Notice of Allowance mailed 6/05/09, U.S. Application No. 12/106,621	

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EXAMINER

/James Rogers/

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